Policy & Procedure (P& P)

Policy Title :		
Irradiation of Blood products		
Department	**Index No.**	**Scope**
Laboratory & Blood Bank	LAB-078	All Blood Bank Staff
Issue Date	**Revision NO**	**Effective Date**
1441/7/14	NEW	1441/7/19
Review Due Date	**Related Standard NO.**	**Page Number#**
1443/7/19	CBAHI (LB.49)	7

01. Policy:

In accordance with AABB standards all patients at risk of developing graft versus host disease GVHD will receive irradiated cellular blood components.

The product will be permanently labeled as irradiated and the expiry of PRBCs will not exceed 28 days

02. Definition :

Irradiated:refers to blood and blood components that have been exposed to gamma radiation.

03. Purpose :

The irradiation of blood products and cellular components is recommended for prevention of graft versus host disease GVHD caused by lymphocytes present in most blood products specially to the immune compromised patients.

04. Procedure :

MATERIALS:

- RAD SOURCE 3400 X-ray Blood Irradiator
- The Rad Source 3400 delivers a minimumof 25 GY to the central part of the canister and a minimum of 15 GY at any point
- The Cycle time for 25 Gy center dose is less than 5 minutes.
- Patented rotator which holds 6 product Canisters.

- 25 Gy blood irradiation indicator label
- Irradiated label

DESCRIPTION

- The RS 3400 is a medical device (FDA 510(k)) which uses X-ray irradiation to irradiate blood and blood products packaged in transfusion bags when irradiation for GVHD is indicated. It uses a single X-ray source and rotates individual canisters around this X-ray source for a specific period of time so that irradiation is delivered to the contents of the canisters

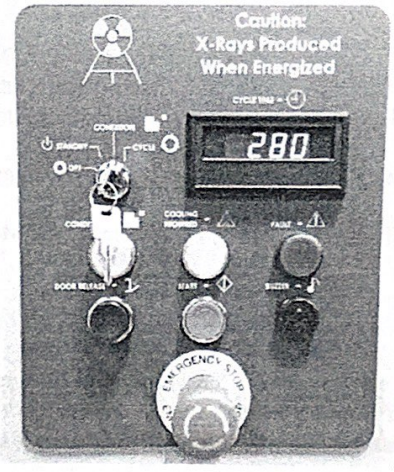
Safety

- The irradiator is only operable with a key that is kept in secure area (senior technologist desk) and only blood bank personnel have access to it
- The irradiated units are placed in an ordinary nylon bag when placed in the stainless steel beaker so to prevent the damage of the machine parts if leakage happens during irradiation.

- **The Rad Source RS 3400 X-Ray blood irradiator is a cabinet X-Ray System according to the US code of Federal Regulations 10 CFR 1020.40 and has a shielding system which ensure external emission levels less than 500 µR/hr at 5 cm from any surface while in operation.**
  Accordingly, there is no requirement to install the RS 3400 in a shielded room and/or to limit the amount of time an operator stays in close to the unit while in operation.

Procedure:

This procedure is followed at each time of use.



1) To open the door

- The blood bank technician holds the Door Release Button and pull the door handle simultaneously.
- Do not open the door when Cycle or Condition Mode is in operation.
- The blood bank technician closes the door gently not to break the door interlock.

2) Condition Mode:

- Condition light automatically turns ``on`` after >= 8 hours of non operation.
- The blood bank technician needs to run Condition mode when Condition light turns ``on``. This mode last 10-15 minutes .
- Gently turn the Key to Condition Mode . The blood bank technician has 3 seconds to push the Start Button.
- WARNING: do not run blood products in Condition Mode. No timer = no blood.

3) Cycle Mode:

- The blood bank techniciangently turns the key to Cycle Mode to run blood products.
- The blood bank technician after crossmatching the unit of PRBCs attaches irradiation indicator label to the product unit.
- The blood bank technician puts the unit of blood in a Ziploc bag then ensures the blood products are inside the canister with the lid closed tightly.
- The blood bank technician inserts Canister into Canister Holder with the lid facing out towards user and pushed behind the springs.
- The blood bank technician only puts canisters with blood products inside the machine to run a cycle.
- All empty canisters remain remain outside the machine to run a cycle.
- PRBCs and Platelets can be run in the same cycle in different canisters.
- At the end of Cycle, the blood bank technician opens the door to turn off the buzzer.
- Do not hit the canister against the X-Ray tube.
- Do not store the Canisters inside the machine at any time.
- Do not need to balance Canisters inside the machine to run a cycle.

4) Fault light and Noise

- The blood bank technician counts 30 seconds when it turns on
- The blood bank technician pushes **the Start Button**
- The Cycle/Time Display should continue from where it stopped when the fault turned on
- Note: Single cycle = 3 faults max.
- If there is a 4th fault, call Support Line 8002440321 and give them the machine code : 5011764 and remove blood products from the machine.
- WARNING: Blood product that do NOT complete a cycle, cannot be used as properly irradiated.

5) Emergency Stop (E-Stop Button)

- Only push E-Stop Button for emergencies involving water, smoke and fire.
- If accidently pushed, release the E-Stop Button and gently turn the key Off Mode.
- Wait 10 seconds and then gently turn Key to Cycle Mode to resume normal operation.

6) **Generator Test**

- Gently turn key off mode before the generator test.
- Gently turn key to Cycle Mode when the generator test is over.

7) **Expiry of the PRBCs :**

- **The expiry of the PRBCs will not exceed 28 days or the original expiry date whichever is first.**
- **Platelets may be irradiated at any time and will retain their original expiry date.**

- Red cells can be irradiated at any time up to 14 days after collection.
- Irradiated units are not radioactive and require no special handling.
- Irradiated components can be transfused to other patients if not transfused to intended recipient.
- For neonates use, it is preferable to use red cell products within 24 hours of irradiation. There may be an increased risk of hyperkaliemia in neonates particularly when large volumes are required eg exchange transfusion.
- Only cellular products (PRBCs and Platelets) require irradiation .
- Frozen products (FFP, Cryoprecipitate) don`t contain viable lymphocytes and do not require irradiation.
- Granulocytes for all recipient should be irradiated as soon as possible after production and therefore transfused with minimal delay.
- If irradiation indicator label is not available, write or attach IRRADIATED label to the unit when taking it out of the irradiator.

Discard the irradiated unit if:

- Irradiation exceed the required time
- Irradiation time is unknown.

QUALITY CONTROL

The biomedical physics performs the following QC checks:

1- Recalculate the decay of the source every six months according to the information given in the operation manual.
2- Monitor the irradiation leakage every six months
3- Required dosage must reach all areas within the product compartment.

INDICATIONS:

Cellular blood components that require irradiation to reduce the risk of graft-versus-host disease include red blood cells, platelets, plateletpheresis and granulocytes-pheresis.

Irradiated blood components are recommended for but are not limited to the following recipients to reduce the risk of TA-GvHD:

1- All individuals with chronic graft-vs-host disease

2- Individuals with congenital cellular immunodeficiency; thymic hypoplasia, Wiskott-Aldrich syndrome, DiGeorge syndrome, infants with congenital cardiac aortic arch defects, severe combined immune deficiency, purine nucleoside phosphorylase deficiency, reticular dysgenesis, and cell-mediated immune deficiency of unspecified etiology.

3- Allogeneic and autologous hematopoietic stem cell transplant recipients.

4- Individuals receiving HLA compatible platelets

5- Individuals with hodgkin's disease or those treated with purine analogs (Cladarbine, Fludarabine, 2-CDA, Penntastatin, Deoxycoforycin).

6- Individuals receiving granulocyte transfusions

7 -All individuals undergoing intrauterine transfusions and neonates who have previously received intrauterine transfusions

8 -Individuals receiving a transfusion from a biological/blood relative.

- **Probable indications for irradiated blood components include:**

1- Infants weighing less than 1200 g at birth

2- Individuals being treated with cytotoxic agents for hematologic malignancies other than hodgkin's disease.

3- Individuals receiving aggressive immunosuppressive therapy (chemotherapy, radiation therapy)

4- Platelet donors chosen for crossmatch compatibility or HLA matching.

- **Controversial indications for irradiated blood components include:**

1- Individuals undergoing solid organ transplant

2- Aplastic anemic individuals not receiving immunosuppressive therapy

3- Term neonates undergoing extracorporeal membrane oxygenation.

- Irradiation of cellular blood components prevents the proliferation of T- lymphocytes and thus prevents T-lymphocytes from invading the recipient's immune system which may cause transfusion associated graft versus host disease.
- Irradiated blood components are required to be exposed to a minimum dose of 25 Gy of gamma irradiation.

- All irradiated blood components will be labelled to indicate that the product has been irradiated, the facility performing irradiation and the expiration date.
- The maximum expiration time for irradiated whole blood and red blood cells is 28 days after irradiation or original expiration date, whichever is shorter.
- Irradiated platelets components retain their original expiration

05. Responsibilities :

All Blood Bank Staff, Serology Staff and Hematology Staff of Al-Qunfudah General Hospital

06. Equipment & Forms

RAD SOURCE 3400 X-ray Blood Irradiator

07. Attachment :

N/A

08. Reference

- Technical Manual of the American Association of Blood Banks, 18th edition, 2014
- The unified practical procedure manual for blood banks in the arab countries, 2013
- Rad Source RS 3400 technical manual

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Ministry of Health
مستشفى القنفذة العام

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